

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : James B. Dale  
Application No. : Not yet assigned  
Filed : February 17, 2004  
For : GROUP A STREPTOCOCCAL VACCINES  
Docket No. : 481112.410C1

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents:


In accordance with 37 C.F.R. §§ 1.56 and 1.97 through 1.98, applicant wishes to make known to the U.S. Patent and Trademark Office the 95 references set forth on the attached Form PTO-1449. This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior Application No. 09/151,409, filed September 10, 1998. All of the references listed on the attached Form PTO-1449, except references listed at AF, AN and AO, were submitted to and/or cited by the Patent and Trademark Office in this prior application and, therefore, are not required to be provided in this application. If the Examiner wishes, copies will be provided upon request. Copies of the references at AF, AN and AO are attached.

As to any reference supplied, applicant does not admit that it is "prior art" under 35 U.S.C. §§ 102 or 103, and specifically reserves the right to traverse or antedate any such reference, as by a showing under 37 C.F.R. § 1.131 or other method. Although the aforesaid references are made known to the Patent and Trademark Office in compliance with applicant's duty to disclose all information he is aware of which is believed relevant to the examination of the above-identified application, applicant believes that his invention is patentable.

Please acknowledge receipt of this Information Disclosure Statement and kindly make the cited references of record in the above-identified application.

Applicant believes this Information Disclosure Statement has been timely filed, however, the Director is authorized to charge any fee due by way of this Information Disclosure Statement to our Deposit Account No. 19-1090.

Respectfully submitted,  
Seed Intellectual Property Law Group PLLC

  
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Registration No. 46,985

Enclosures:  
Form PTO-1449 (9 pages)  
References (3)

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FORM PTO-1449 (REV.7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. <b>481112.410C1</b>	APPLICATION NO.
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*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	4,284,537	08/18/81	Beachey	260	6	
	AB	4,454,121	06/12/84	Beachey	424	177	
	AC	4,521,334	06/04/85	Beachey	260	112.5 R	
	AD	4,597,967	07/01/86	Beachey	424	88	
	AE	4,705,684	11/10/87	Beachey	424	88	
	AF	<b>4,784,948</b>	<b>11/15/88</b>	<b>Scott et al. [copy enclosed]</b>	<b>435</b>	<b>68</b>	
	AG	4,919,930	04/24/90	Beachey et al.	424	88	
	AH	5,124,153	06/23/92	Beachey et al.	424	93	
	AI	5,334,379	08/02/94	Pillai et al.	424	85.2	
	AJ	5,985,654	11/16/99	Fischetti et al.	435	320.1	
	AK	6,063,386	05/16/00	Dale et al.	424	244.1	
	AL	6,419,932	07/16/02	Dale	424	244.1	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AM	WO 94/06421	03/31/94	PCT		
	AN	<b>WO 94/06465</b>	<b>03/31/94</b>	<b>PCT [copy enclosed]</b>		
	AO	<b>WO 00/37648</b>	<b>06/29/00</b>	<b>PCT [copy enclosed]</b>		

OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	AP	Ada, <i>Fundamental Immunology</i> , William E. Paul, M.D. (ed.), 2 <sup>nd</sup> Edition, Raven Press, New York, 1989, pp. 1010-1011.
	AQ	Baird et al., "Epitopes Of Group A Streptococcal M Protein Shared With Antigens Of Articular Cartilage And Synovim," <i>The Journal Of Immunology</i> 146(9):3132-3137, 1991.
	AR	Beachey and Ofek, "Epithelial Cell Binding Of Group A Streptococci By Lipoteichoic Acid On Fimbriae Denuded Of M Protein," <i>The Journal Of Experimental Medicine</i> 143:759-771, 1976.

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	BA						
<b>FOREIGN PATENT DOCUMENTS</b>							
		DOCUMENT NUMBER	DATE	COUNTRY		TRANSLATION	
						YES	NO
	BB						
<b>OTHER PRIOR ART</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
	BC	Beachey and Seyer, "Protective And Nonprotective Epitopes Of Chemically Synthesized Peptides Of The NH <sub>2</sub> -Terminal Region Of Type 6 Streptococcal M Protein," <i>The Journal Of Immunology</i> 136(6):2287-2292, 1986.					
	BD	Beachey and Seyer, <i>Seminars in Infectious Disease. Volume IV Bacterial Vaccines</i> , Thieme-Stratton Inc., New York, New York, 1982, Chapter Fifty-Seven, "Primary Structure And Immuno-Chemistry Of Group A Streptococcal M Proteins," pp. 401-410.					
	BE	Beachey and Stollerman, "Mediation of Cytotoxic Effects of Streptococcal M Protein by Nontype-Specific Antibody in Human Sera," <i>The Journal of Clinical Investigation</i> 52:2563-2570, 1973.					
	BF	Beachey and Stollerman, "Toxic Effects Of Streptococcal M Protein On Platelets And Polymorphonuclear Leukocytes In Human Blood," <i>The Journal Of Experimental Medicine</i> 134:351-365, 1971.					
	BG	Beachey et al., "Human Immune Response To Immunization With a Structurally Defined Polypeptide Fragment Of Streptococcal M Protein," <i>J. Exp. Med.</i> 150:862-877, 1979.					
	BH	Beachey et al., "Immunogenicity In Animals And Man Of A Structurally Defined Polypeptide Of Streptococcal M Protein," <i>Transactions Of The Association Of American Physicians, Volume XCII</i> :pp.346-354, 1979.					
	BI	Beachey et al., "Opsonic Antibodies Evoked By Hybrid Peptide Copies Of Types 5 and 24 Streptococcal M Proteins Synthesized In Tandem," <i>J. Exp. Med.</i> 163: 1451-1458, 1986.					
	BJ	Beachey et al., "Peptic Digestion of Streptococcal M Protein. II. Extraction of M Antigen from Group A Streptococci With Pepsin," <i>Infection And Immunity</i> 9(5):891-896, 1974.					
	BK	Beachey et al., "Primary Structure of Protective Antigens of Type 24 Streptococcal M Protein," <i>The Journal Of Biological Chemistry</i> 255(13):6284-6289, 1980.					
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	CA						
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						YES	NO
	CB						
<b>OTHER PRIOR ART</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
	CC	Beachey et al., "Protective Immunogenicity And T Lymphocyte Specificity Of A Trivalent Hybrid Peptide Containing NH <sub>2</sub> -Terminal Sequences Of Types 5, 6, And 24 M Proteins Synthesized In Tandem," <i>The Journal Of Experimental Medicine</i> 166:647-656, 1987.					
	CD	Beachey et al., "Purification And Properties Of M Protein Extracted From Group A Streptococci With Pepsin: Covalent Structure Of The Amino Terminal Region Of Type 24 M Antigen," <i>The Journal Of Experimental Medicine</i> 145:1469-1483, 1977					
	CE	Beachey et al., "Repeating Covalent Structure and Protective Immunogenicity of Native and Synthetic Polypeptide Fragments of Type 24 Streptococcal M Protein," <i>The Journal Of Biological Chemistry</i> 258(21):13250-13257, 1983.					
	CF	Beachey et al., "Repeating covalent structure of streptococcal M protein," <i>Proc. Natl. Acad. Sci. USA</i> 75(7):3163-3167, 1978.					
	CG	Beachey et al., "Separation Of The Type Specific M Protein From Toxic Cross Reactive Antigens Of Group A Streptococci," <i>Transactions Of The Association Of American Physicians. Ninetieth Session Volume XC: pp. 390-400, 1977.</i>					
	CH	Beachey et al., "Type-specific protective immunity evoked by synthetic peptide of <i>Streptococcus pyogenes</i> M Protein," <i>Nature (London)</i> 292:457-459, 1981.					
	CI	Beall et al., "Sequencing <i>emm</i> -Specific PCR Products for Routine and Accurate Typing of Group A Streptococci," <i>Journal of Clinical Microbiology</i> 34(4):953-958, April 1996.					
	CJ	Blenden et al., "Growth of <i>Listeria monocytogenes</i> in a Corn Silage Extract Medium," <i>American Journal Of Veterinary Research</i> 29(11):2237-2242, 1968.					
	CK	Bricas et al., "Structure Et Synthese De La Subunite Peptide De La Paroi De Trois Bacteries Gram-Postif," <i>Peptides. Proceedings of the Eight European Peptide Symposium September 1966, Noordwijk, Neth.</i> , North-Holland Publishing Company: Amsterdam, Neth. And Interscience Publishers Division, John Wiley and Sons, Inc., New York, 1967, 286-292 (+ <i>Biological Abstracts</i> 50(4):Abstract No. 20361, 1936).					
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						YES	NO
	DB						
<b>OTHER PRIOR ART</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
	DC	Bronze et al., "Protective And Heart-Cross Reactive Epitopes Located Within The NH <sub>2</sub> Terminus Of Type 19 Streptococcal M Protein," <i>The Journal Of Experimental Medicine</i> 167:1849-1859, 1988.					
	DD	Chou and Fasman, "Prediction of Protein Conformation," <i>Biochemistry</i> 13(2):222-245, 1974.					
	DE	Cunningham and Beachey, "Peptic Digestion of Streptococcal M Protein. I. Effect of Digestion at Suboptimal pH upon the Biological and Immunochemical Properties of Purified M Protein Extracts," <i>Infection And Immunity</i> 9(2):244-248, 1974.					
	DF	Cunningham et al., "Human And Murine Antibodies Cross-Reactive With Streptococcal M Protein And Myosin Recognize The Sequence Gln-Lys-Ser-Lys-Gln In M Protein," <i>The Journal Of Immunology</i> 143(8):2677-2683, 1989.					
	DG	Dale, "Group A Streptococcal Vaccines," <i>New Vaccines And New Vaccine Technology</i> 13(1):227-243, 1999.					
	DH	Dale, "Group A Streptococcal Vaccines," <i>Pediatric Annals</i> 27:301-308, 1998.					
	DI	Dale, "Multivalent group A streptococcal vaccine designed to optimize the immunogenicity of six tandem M protein fragments," <i>Vaccine</i> 17:193-200, 1999.					
	DJ	Dale and Beachey, "Multiple, Heart-Cross-Reactive Epitopes Of Streptococcal M Proteins," <i>Journal Of Experimental Medicine</i> 161:113-122, January 1985.					
	DK	Dale and Beachey, "Epitopes Of Streptococcal M Proteins Shared With Cardiac Myosin," <i>The Journal Of Experimental Medicine</i> 162:583-591, 1985.					
	DL	Dale and Beachey, "Localization Of Protective Epitopes Of The Amino Terminus Of Type 5 Streptococcal M Protein," <i>The Journal Of Experimental Medicine</i> 163:1191-1202, 1986.					
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	EB						
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	EC	Dale and Beachey, "Sequence Of Myosin-Crossreactive Epitopes Of Streptococcal M Protein," <i>Journal Of Experimental Medicine</i> 164:1785-1790, 1986.					
	ED	Dale et al., "Heterogeneity Of Type-Specific And Cross-Reactive Antigenic Determinants Within A Single M Protein Of Group A Streptococci," <i>The Journal Of Experimental Medicine</i> 151:1026-1038, 1980.					
	EE	Dale et al., "Blastogenic Responses Of Human Lymphocytes To Structurally Defined Polypeptide Fragments Of Streptococcal M Protein," <i>The Journal Of Immunology</i> 126(4):1499-1505, 1981.					
	EF	Dale et al., "Type-Specific Immunogenicity Of A Chemically Synthesized Peptide Fragment Of Type 5 Streptococcal M Protein," <i>The Journal Of Experimental Medicine</i> 158:1727-1732, 1983.					
	EG	Dale et al., "Recombinant Tetravalent Group A Streptococcal M Protein Vaccine," <i>Journal of Immunology</i> 151(4):2188-2194, August 15, 1993.					
	EH	Dale et al., "Intranasal immunization with recombinant group A streptococcal M protein fragment fused to the B subunit of Escherichia coli labile toxin protects mice against systemic challenge infections," <i>Journal of Infectious Diseases</i> 171(4):1038-1041, April 1995 (abstract).					
	EI	Dale et al., "Hyaluronate Capsule and Surface M Protein in Resistance to Opsonization of Group A Streptococci," <i>Infection And Immunity</i> 64(5):1495-1501, 1996.					
	EJ	Dale et al., "New protective antigen of group A streptococci," <i>J. Clin. Invest.</i> 103(9):1261-1268, 1999.					
	EK	Dale et al., "Recombinant, octavalent group A streptococcal M protein vaccine", <i>Vaccine</i> 14(10):944-948, July 1996.					
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	FB						
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	FC	Dixit et al., "Covalent Structure of Collagen: Amino Acid Sequence of $\alpha 1$ -CB6A of Chick Skin Collagen," <i>Biochemistry</i> 14(9):1933-1938, 1975.					
	FD	Edman and Begg, "A Protein Sequenator," <i>European J. Biochem.</i> 1:80-91, 1967.					
	FE	Fischetti et al., "Surface Proteins form Gram-Positive Cocci Share Unique Structural Features," in Orefici (ed.), <i>New Perspectives on Streptococci and Streptococcal Infections. Proceedings of the XI Lancefield International Symposium on Streptococci and Streptococcal Diseases</i> , Siena, Italy, September 10-14, 1990, Gustav Fischer verlag, Stuttgart, Jena, New York, 1992, pp. 165-167.					
	FF	Fischetti, "Streptococcal M Protein," <i>Scientific American</i> :pp. 58-65, 1991.					
	FG	Fischetti et al., "Protection Against Streptococcal Pharyngeal Colonization with a Vaccinia: M Protein Recombinant," <i>Science</i> 244:1487-1490, 1989.					
	FH	Freimer and McCarty, "Rheumatic Fever," <i>Scientific American</i> 213(6):67-74, 1965.					
	FI	Gibbons et al., "Studies of Individual Amino Acid Residues of the Decapeptide Tyrocidine A by Proton Double-Resonance Difference Spectroscopy in the Correlation Mode," <i>Biochemistry</i> 14(2):420-437, 1975.					
	FJ	Goldsberg et al., "Serological Demonstration of H-Y (Male) Antigen on Mouse Sperm," <i>Nature</i> 232:478-480, 1971.					
	FK	Hollingshead et al., "Complete Nucleotide Sequence of Type 6 M Protein of the Group A <i>Streptococcus</i> ," <i>The Journal Of Biological Chemistry</i> 261(4):1677-1686, 1986.					
	FL	Hopp and Woods, "Prediction of protein antigenic determinants from amino acid sequences," <i>Proc. Natl. Acad. Sci. USA</i> 78(6):3824-3828, 1981.					
	FM	Hruby et al., "Assembly and analysis of a functional vaccinia virus 'amplicon' containing the C-repeat region from the M protein of <i>Streptococcus pyogenes</i> ," <i>Procedures of the National Academy of Sciences USA</i> 88:3190-3194, April 1991.					
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	GB						
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	GC	Jones et al., "Differential Effects Of Antibodies To Lyt-2 And L3 T4 On Cytolysis By Cloned, Ia-Restricted T Cells Expressing Both Proteins," <i>The Journal Of Immunology</i> 139(2):380-384, 1987.					
	GD	Kang, "Studies on the Location of Intermolecular Cross-Links in Collagen. Isolation of a CNBr Peptide Containing $\delta$ -Hydroxylysine norleucine," <i>Biochemistry</i> 11(10):1828-1835, 1972.					
	GE	Kang and Gross, "Amino Acid Sequence of Cyanogen Bromide Peptides from the Amino-Terminal Region of Chick Skin Collagen," <i>Biochemistry</i> 9(4):796-804, 1970.					
	GF	Kaplan et al., "Group A Streptococcal Serotypes Isolated from Patients and Sibling Contacts During the Resurgence of Rheumatic Fever in the United States in the Mid-1980s," <i>The Journal Of Infectious Diseases</i> 159(1):101-103, 1989.					
	GG	Koch et al., "Purification And Structural Analysis Of Streptolysin S (SLS)," <i>Federation Proceedings</i> 42(7): p. 1810, Abstract No. 309, 1983.					
	GH	Kraus et al., "Identification Of An Epitope Of Type 1 Streptococcal M Protein That Is Shared With A 43-kDa Protein Of Human Myocardium And Renal Glomeruli," <i>The Journal Of Immunology</i> 145(12):4089-4093, 1990.					
	GI	Kraus et al., "Sequence And Type-Specific Immunogenicity Of The Amino-Terminal Region Of Type 1 Streptococcal M Protein," <i>The Journal Of Immunology</i> 139(9):3084-3090, 1987.					
	GJ	Lancefield, "Persistence Of Type-Specific Antibodies In Man Following Infection With Group A Streptococci," <i>J. Exp. Med.</i> 110:271-292, 1959.					
	GK	Laver et al., "Antigenic drift in type A influenza virus: Peptide mapping and antigenic analysis of A/PR/8/34 (HON1) variants selected with monoclonal antibodies," <i>Proc. Natl. Acad. Sci. USA</i> 76(3):1425-1429, 1979.					
	GL	Lockey, "Urticaria of Unknown Origin," <i>Hospital Practice</i> : pp. 49-57, 1979.					
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						YES	NO
	HB						
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	HC	Manjula and Fischetti, "Tropomyosin-Like Seven Residue Periodicity In Three Immunologically Distinct Streptococcal M Proteins And Its Implications For The Antiphagocytic Property Of The Molecule," <i>J. Exp. Med.</i> 151:695-708, 1980.					
	HD	Marston and Hartley, "Solubilization of Protein Aggregates," in <i>Methods in Enzymology, Guide to Protein Purification</i> , ed. MP Deutscher, vol. 182, section 20, pp. 264-276, 1991.					
	HE	Miller et al., "Antigenic Variation among Group A Streptococcal M Proteins," <i>The Journal Of Biological Chemistry</i> 263(12):5668-5673, 1988.					
	HF	Miller et al., "Conservation of Protective and Nonprotective Epitopes in M Proteins of Group A Streptococci," <i>Infection And Immunity</i> 56(8):2198-2204, 1988.					
	HG	Mori et al., "Persistent Elevation of ImmunoglobulinG Titer against the C Region of Recombinant Group A Streptococcal M Protein in Patients with Rheumatic Fever," <i>Pediatric Research</i> 39(2): 336-342, 1996.					
	HH	Mouw et al., "Molecular Evolution of Streptococcal M Protein: Cloning and Nucleotide Sequence of the Type 24 M Protein Gene and Relation to Other Genes of <i>Streptococcus pyogenes</i> ," <i>Journal Of Bacteriology</i> 170(2):676-684, 1988.					
	HI	Phillips, Jr. et al., "Streptococcal M protein: $\alpha$ -Helical coiled-coil structure and arrangement on the cell surface," <i>Proc. Natl. Acad. Sci. USA</i> 78(8):4689-4693, 1981.					
	HJ	Podbielski et al., "Application of the polymerase chain reaction to study the M protein(-like) gene family in beta-hemolytic streptococci," <i>Med. Microbiol. Immunol.</i> 180:213-227, 1991.					
	HK	Rijn et al., "Group A Streptococcal Antigens Cross-Reactive With Myocardium," <i>The Journal of Experimental Medicine</i> 146:579-599, 1977.					
	HL	Robbins et al., " <i>Streptococcus pyogenes</i> Type 12 M Protein Gene Regulation by Upstream Sequences," <i>Journal Of Bacteriology</i> 169(12):5633-5640, 1987.					
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<b>* EXAMINER:</b> Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).							

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. <b>481112.410C1</b>		APPLICATION NO.	
<b>INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>				APPLICANT <b>James B. Dale</b>			
				FILING DATE <b>February 17, 2004</b>		GROUP ART UNIT	
<b>U.S. PATENT DOCUMENTS</b>							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	IA						
<b>FOREIGN PATENT DOCUMENTS</b>							
		DOCUMENT NUMBER	DATE	COUNTRY		TRANSLATION	
						YES	NO
	IB						
<b>OTHER PRIOR ART</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
	IC	Sargent et al., 'Sequence Of Protective Epitopes Of Streptococcal M Proteins Shared With Cardiac Sarcolemmal Membranes,' <i>The Journal Of Immunology</i> 139(4):1285-1290, 1987.					
	ID	Seyer and Kang, "Covalent Structure of Collagen: Amino Acid Sequence of Cyanogen Bromide Peptides from the Amino-Terminal Segment of Type III Collagen of Human Liver," <i>Biochemistry</i> 16(6):1158-1164, 1977.					
	IE	Seyer et al., "Primary Structural Similarities Between Types 5 And 24 M Proteins Of Streptococcus pyogenes," <i>Biochemical And Biophysical Research Communications</i> 92(2):546-553, 1980.					
	IF	Smithies et al., "Quantitative Procedures for Use with the Edman-Begg Sequenator. Partial Sequences of Two Unusual Immunoglobulin Light Chains, RzF and Sac," <i>Biochemistry</i> 10(26):4912-4921, 1971.					
	IG	Vashishtha et al., Reactivity of Antisera to Peptides Corresponding to the C-repeat Region of Streptococcal M Protein with Mammalian Coiled-Coil Proteins," <i>Abstracts Of The 91<sup>st</sup> General Meeting of the Society for Microbiology</i> 1991:p. 129, Abstract No. E-66, 1991					
	IH	Vashishtha and Fischetti, "Surface-Exposed Conserved Region of the Streptococcal M Protein Induces Antibodies Cross-Reactive with Denatured Forms of Myosin," <i>Journal of Immunology</i> 150(10):4693-4701, May 15, 1993.					
	II	Weigent et al., "Induction of Human Gamma Interferon by Structurally Defined Polypeptide Fragments of Group A Streptococcal M Protein," <i>Infection And Immunity</i> 43(1):122-126, 1984.					
	IJ	Wistedt et al., "Identification of a plasminogen-binding motif in PAM, a bacterial surface protein," <i>Molecular Microbiology</i> 18(3): 569-578, 1995.					
	IK	Wittner and Fox, "Homologous and Heterologous Protection of Mice with Group A Streptococcal M Protein Vaccines," <i>Infection and Immunity</i> 15(1):104-108, January 1977.					
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